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¶1. (SBU) SUMMARY: Jordan's $330 million pharmaceutical industry is a bright spot in the nation's industrial development and one of the front-runner sectors in the leadership's strategy of export-led economic growth. Hikma Pharmaceuticals and its parent, the Hikma Group, is the shining star among the constellation of 18 pharmaceutical companies in Jordan. Like the rest of Jordan's industry, Hikma is a generic-drug firm, producing drugs that are off-patent. But Hikma offers value added through novel delivery systems, developed with a strong R&D base. Hikma boasts U.S. FDA approval for virtually all of its manufacturing plants - stretching from Saudi Arabia to Algeria to Portugal and the United States, where it owns West-ward Pharmaceuticals. Hikma, which just acquired majority control of Saudi and Italian drug firms, listed on the London Stock Exchange (LSE) last November and will list on the Dubai exchange this month.

¶2. (SBU) With access to 34 markets, Hikma is one of the leading pharma companies in the Middle East and North Africa (MENA) region, and the 12th largest generic-drug company in the world. Hikma is primed to take advantage of the rise in generic sales worldwide, as more than 30 major drugs come off patent in the next five years. However, for the dream of novel drug development to be realized in a major way, Jordan needs to move to a higher plane of R&D infrastructure, develop advanced life sciences education and research, and undergo cultural shifts in areas such as government and philanthropic support for research. END SUMMARY.

Next Stop: NASDAQ

¶3. (SBU) Hikma (Jordan) CEO Mazen Darwazeh, who is proud of the recent LSE listing for a capitalization of $1.2 billion, would like some day to be on the NASDAQ. For now, the costs are prohibitive, he told Econoff - three times the cost of listing in London. (He cited Sarbanes-Oxley requirements as a costly inhibitor to a NASDAQ listing.) The LSE and Dubai

market capitalization will allow Hikma to pursue new growth opportunities in areas such as injectable drugs - a major earner in 2005 in the U.S. and in European markets - and to build on its strength in the MENA region.

¶4. (U) Hikma Group Chairman Samih Darwazeh began as a small drug-store owner 27 years ago in Amman. His is among a prominent group of Palestinian business families who made it in Jordan, and whose businesses are positioned to take off under Jordan's liberalized economic policy structure. As Samih put it, it took over a quarter century to gain a strong foothold in MENA's "fragmented market." Hikma in the next few years will seek to expand its 140-product base to reach the MENA region's youthful population and rapidly growing health care markets, especially in the GCC countries, a proposition made more profitable by the region's lower tax base compared to Europe and the U.S. From a small family business, Hikma has grown to have over 700 employees in Jordan, with 1100 more employees throughout the world, including 302 in the U.S., according to CEO Mazen. Overall employment in the pharmaceutical sector in Jordan is close to 5,000. Note: Pharmaceutical company jobs are considered more prestigious by Jordanians than jobs in other export industries, such as garments or marble stone. In this sense, pharmaceuticals present a concrete picture to Jordan's trade and investment leaders of where they want to go with industrial growth, and explains in part the current fascination with science-technology development. End Note.

¶5. (SBU) Hikma is an example of Jordan's success in the pharmaceuticals industry in the region. Last year, total pharmaceutical production in Jordan was $330 million, of which domestic-targeted production accounted for only 15

percent. With exports of $280 million in 2005, pharmaceutical products account for 8 percent of all of Jordan's exports. Over the last 50 years, Jordanian firms developed major inroads into the Iraqi market, for example. This situation quickly reversed in 2003 when drug exports to Iraq dropped by 75% to less than $10 million. Jordan's major drug markets now are Saudi Arabia, Algeria, Iraq, and Sudan. But many of the generic-drug firms have licensing agreements with small factories throughout the MENA region, bringing Jordan's generic-drug manufacturing know-how to partnerships that gain market access to other countries. Hikma has a respectable 3.5 percent share of the entire Saudi market, and is ranked number 6 and the leading generic-drug firm there. In Algeria, Hikma boasts a 3.2 percent market share; it is the 7th ranked company and second-largest generic firm.

One of Few Arab Firms in MENA with FDA Approval

¶6. (SBU) The company's ability to master the rigorous U.S. FDA approval process has been one advantage. Hikma factories first secured FDA approval in 1994; Israel's Teva Pharmaceuticals was the only other generic-firm in the region to do so. Up through an investors meeting at the end of March, Samih Darwazeh was touting Hikma as the "only Arab" firm with FDA approval in MENA, a claim that Hikma CEO Mazen thinks will not last the year, as a few other mature MENA pharmaceutical companies complete the FDA approval process. This past January, Hikma succeeded in securing FDA approval for a Saudi-based cephalosporin plant of its wholly-owned Subsidiary, Jazeera Pharmaceutical Industries. Other companies in Jordan are looking to follow suit with FDA inspections, although one informed observer remarked to Econoff that the majority of Jordanian firms will have to overcome a contrary culture - so oriented are they to short-term profits over a long-term strategy. According to Samih Darwazeh, Hikma's attention to quality makes it the "partner of choice for multinationals" in the MENA region.

Licensing Agreements - Wave of the Future?

¶7. (SBU) A case in point is Hikma's licensing agreement with Eli Lilly to market the brand Cialis (tadalafil) for erectile dysfunction. Hikma places the drug throughout its markets in the MENA region, although Lilly still manufactures the pills and continues to hold the data exclusivity-registration rights. Hikma pays Lilly a royalty on its Cialis sales. Most Jordanian companies would not have the sales force or marketing tools to handle this type of drug placement. They would just prefer to follow their short-term success models: secure the manufacturing rights and bring the drug molecule to the markets they already have, according to a PhRMA observer.

¶8. (SBU) However, the number two pharmaceutical company in Jordan - Dar Al Dawa - reportedly has a similar licensing arrangement with Novartis, and observers expect more such deals in the future. It remains to be seen if these licensing deals can cross over to a generic manufacturing scheme by which originator companies share their formulae and processes in return for some control of their drugs' market access even beyond the patent life.

Hikma R&D and Jordan's R&D Needs

¶9. (SBU) In 2005, Hikma devoted $16.5 million to R&D out of total revenues of $262.2 million, over 6% of revenues. CEO Mazen Darwazeh said that two R&D centers are being developed in Jordan and in the U.S., mainly to discover new delivery systems and develop new formulations or dosages of off-patent drugs. Injectables are a big focus of Hikma's research. Mazen stated that the average R&D expenditure on drugs in Jordan was about 2% of gross revenues, well above the Arab world's 0.8% of GDP. He boasted that Hikma had over 120 technicians working on research, with more than 20 PhD's. For all of Hikma's commitment to R&D, Mazen emphasized that he did not see Hikma going down the path of novelty drug R&D

for at least another five years. Jordan was at least a decade away from developing even the most basic novelty drug R&D, he stated. Even then, Jordan was better positioned than most in the MENA region to develop R&D for breakthrough drugs, he said.

¶10. (SBU) The Hikma CEO commented that Jordan had a long to-do list to develop its already flourishing pharma industry to the next level. Jordan must devote major resources to a life sciences research center, one that he thought should be centrally located rather than spread out among Jordan's half-dozen technical universities. (Note: Jordan has eight colleges of pharmacy; the most advanced at the University of Jordan may soon move to devote all of its resources to just a pharmaceutical doctoral program. End Note.) In addition to inculcating a spirit of inquiry at all levels of the educational system, Jordan would have to develop stronger support for basic research and develop financial incentives, as well.

¶11. (SBU) Mazen Darwazeh cited two key parts of a comprehensive pharmaceutical R&D program: tax incentives for the research, and government funding for selected sectors such as biotechnology. In Ireland, he said, the government provided 1-to-1 matching funds for pharmaceutical R&D. In the meantime, Hikma would pursue the new and growing opportunities in the off-patent world. Hikma's legal counsel indicated that approach meant that even sophisticated Hikma - with so much going for it and so many options to pursue - would stand to benefit in the short run from a "narrow" interpretation of the Jordan-U.S. FTA on points such as "new uses", a subject that the counsel acknowledged remains to be determined in bilateral talks (see ref's).
HALE